UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,991	11/22/2005	Paul James Davis	056222-5094	5135

9629 7590 09/03/2008

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	PAPER NUMBER
1651	
MAIL DATE	DELIVERY MODE
09/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/557,991	DAVIS ET AL.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *11 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-26* is/are pending in the application.

4a) Of the above claim(s) *18-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9 and 11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office Action is in response to the Applicant's reply received 3/11/08. Claims 1-9, 11-26 are pending. Claims 18-26 are withdrawn. Claims 10 and 11 are cancelled. Claims 1, 2 and 11 have been amended. Claim 26 is new.

Election by Original Presentation

Newly submitted claim 26 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Unity of invention was broken in a previous office action mailed 8/8/07. The applicant elected group I, the composition and not the methods of using the composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 26 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Applicant's Arguments

In the response submitted by the Applicant the 35 U.S.C § 101 rejection of claims 1, 2, 4, 5, 8, 9, 12 and 16 is withdrawn. Also the 102 (b) rejection of claims 1, 2, 4, 5, 8, 9, 12 and 16 based on Yoshinaga et al. is withdrawn in light of Applicant's amendment. Also all 35 U.S.C § 103 rejections using Yoshinaga et al. as the primary reference are also withdrawn in light of Applicant's amendment. The 35 U.S.C § 112 rejection of claim 2 is withdrawn in light of the Applicant's amendment. In summary all previous rejections are withdrawn due to Applicant's amendments to the claims.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 8 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakai et al. (U.S. Patent # 5445042).

These claims are drawn to a composition comprising an enzyme, a source of lactate ions, a source of zinc ions and ammonium ions sufficient to maintain activity of the enzyme after radiation sterilization. This claim is a product by process. However M.P.E.P. § 2113 states "product-by process claims" such as this "are not limited to the manipulations of the recited steps, only the structure implied by the steps" as cited below:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Therefor the limitation of "a composition has been subjected to sterilizing irradiation" is a product by process limitation and is still anticipated by other art teaching a sterile composition even if the sterilization was performed by other means. Any composition with the above components will meet the limitation of "sufficient to maintain activity of the enzyme after radiation sterilization" since the necessary structure of the composition (the components) is present. Any composition with the components listed will anticipate the claims since the limitation that the components be in an amount "sufficient to maintain activity of the enzyme after radiation sterilization" is broad, since no direction is provided in the claims or indicated with sufficient specificity (M.P.E.P. § 2131.03) in the specification directly indicating these critical concentration ranges and effectively reads on any amount of these components. Indeed the applications specification provides only suggestions as to the concentration of these components and not clear ranges. The Applicant specification uses open language when referring to the concentration of the components such as "Particularly good results may be obtained when zinc L-lactate is present at a concentration of about 1.0% by weight" (Specification, page 6, lines 3-4) or "ammonium ions may be present at a concentration of at least 0.5 %, preferably at least 1 %, and more preferably at least 2%, by weight" are not specific ranges because they use such relative terms like "may be present" or "preferably at least" which while not indefinite reads on ranges greater then the number indicates (M.P.E.P. § 2173.05 (b)) and thus can be anticipated until such specificity of ranges required to "maintain activity of the enzyme after radiation sterilization" is limited or provided by the Applicant.

Sakai et al. teaches an composition comprising the enzymes trypsin,

chymotrypsin or bromelaine (col 20 line 20) as well as other proteins such as interferons (col 20, lines 28) that are in a wet active state in the aqueous composition (Abstract).This composition has salts that are a source of lactate ions and zinc ions (col 17, lines 20-25) and inherently capable of releasing said ions when immersed in water. Their composition can also comprise alcohols such as ethanol and isopropanol to make the composition sterile and sugar alcohols such as glycerin (col 4, lines 33-45 and col 18 and 19)) as well as a source of ammonium ions (col 17, line 25). Also claim 11 is anticipated since the only limitation it provides to independent claim 1 is that the sterilizing radiation is gamma radiation which mentioned above is a product by process limitation and since Sakai et al. also teach a sterile end product the composition is anticipated. Therefore the reference anticipates claims 1, 2, 4, 5, 8, 9 and 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. as applied to 1, 2, 4, 5, 8, 9 and 11 above and for the following rational.

The description and rejection of claims 1, 2, 4, 5, 8 and 9 are listed in the above 35 U.S.C § 102(b) rejection. Claims 3, 6 and 7 further limit the zinc and lactate components. Claim 11 limits that the sterilizing radiation is gamma radiation.

As mentioned above Claim 11 is a product by process and since the composition of Sakai et al. is sterile the process used to achieve that composition is given little patentable weight and is obvious since both gamma radiation and alcohol sterilization would achieve the same result of a sterilized solution (M.P.E.P. § 2144.07).

While Sakai et al. teaches that their composition can comprise AMPS (col 23, line 24) they do not teach the ammonium salt of AMPS. However considering that Sakai et al. teach other ammonium salts (col 17, lines 20-25) can be used in their composition and that the ammonium salt of AMPS will dissociate in water to ions it would have been obvious to someone skilled in the art to replace the acid version of AMPS in Sakai et al. with the ammonium salt of AMPS since it is well known in the art to replace the acid version of molecules with their salt derivatives and still achieve the same purpose (M.P.E.P. § 2144.06 and M.P.E.P. § 2144.07).

Also Sakai et al. does teach a source of zinc ions and a source of lactate ions but does not specifically teach the salt zinc lactate. However Sakai does teach that a combination of metal salts of organic acids is possible. They teach that their composition may comprise "organic acid salts such as lactate, citrate, tartarate, fumarate, maleate, methanesulfonate; metal salts such as sodium salt, potassium salt, calcium salt, zinc salt)" (col 25, lines 35-40). One of ordinary skill in the art would recognize that metal salts and the salts of organic acids rapidly dissolve in water and exist in the composition as dissociated ions. Therefore it would have been obvious to someone skilled in the art to add zinc lactate to they composition of Sakai et al. since they already have zinc ions and lactate ions in their composition and in an aqueous

solution they would be art recognized equivalents for the same purpose (M.P.E.P. § 2144.06 and 2144.07) since they both dissociate into the same ions.

Furthermore while Sakai et al. does not specifically teach that the lactate used is L-lactate this would be obvious to one of ordinary skill in the art. It is well known in the art that L-lactate is the only bioactive isomer of lactate. Since Sakai et al. teaches a pharmaceutical composition for administration to a human it would be obvious to use the bioactive isomer L-lactate in the composition since this is the simple substitution of one known bioactive element for one that has no bioactivity in a pharmaceutical composition (KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007)). Therefore the references listed above renders obvious claims 1-9 and 11.

Claims 1-9 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. as applied to claims 1-9 and 11 above, and further in view of Green (WO 01/28600).

These claims limit the enzyme in the composition either to glucose oxidase, catalase or lactoperoxidase. While Sakai et al. does teach a wound healing composition that renders obvious the addition of zinc lactate and other salts of lactate such as sodium lactate (col 20 lines 25-40) and ammonium AMPS they do not teach there their enzyme is glucose oxidase, catalase or lactoperoxidase. However this would be obvious to one of ordinary skill in the art in view of Green. Green also teaches a wound healing composition that includes glucose oxidase, lactoperoxidase (Green,

Abstract) and can also comprise catalase (Green pg 11, lines 20-30). M.P.E.P. § 2144.06 states

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to combine the composition of Sakai et al. to the composition of Green since both are wound healing compositions. Therefore the references listed above renders obvious claims 1-9 and 11-17.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Thane Underdahl
Art Unit 1651

Leon B. Lankford Jr
Primary Examiner
Art Unit 1651